P&T Committee Meeting Minutes
Medicaid
January 16, 2024

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Jeremy Bennett, MD
Amir Antonius, Pharm.D.	Kim Castelnovo, RPh
Emily Antosh, Pharm.D.	Michael Evans, RPh
Kristen Bender, Pharm.D.	Nichole Hossler, MD
Alyssa Cilia, RPh	Kelli Hunsicker, Pharm.D.
Kimberly Clark, Pharm.D.	Perry Meadows, MD
Bhargavi Degapudi, MD	Jonas Pearson, RPh
Michael Dubartell, MD	William Seavey, Pharm.D.
Kelly Faust, Pharm.D.	Angela Scarantino
Tricia Heitzman, Pharm.D.	Kristen Scheib, Pharm.D.
Jason Howay, Pharm.D.	Michael Shepherd, MD
Keith Hunsicker, Pharm.D.	Robert Strony, MD MBA
Derek Hunt, Pharm.D.	
Emily Jacobson, Pharm.D.	
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Jamie Miller, RPh	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Kirsten Smith, Pharm.D.	
Aubrielle Smith-Masri Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Luke Sullivan, DO	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Benjamin Andric, PharmD. (non-voting participant)	
Birju Bhatt, MD (non-voting participant)	
Alfred Denio, MD (non-voting participant)	
Keri Donaldson (non-voting participant)	
Jeremy Garris, Pharm.D. (non-voting participant)	
Chidubem Ifeji (pharmacy resident)	

Hailey Knittle (pharmacy resident) Kristen Mascaritola (pharmacy resident) Andrei Nemoianu (non-voting participant)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, January 16, 2024.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the November 21, 2023 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Sohonos (palovarotene)

Review: Sohonos is a retinoid indicated for reduction in the volume of new heterotopic ossification in adults and children aged 8 years and older for females and 10 years and older for males for fibrodysplasia ossificans progressive (FOP). In patients with FOP, abnormal bone formation (including heterotrophic ossification (HO)) is caused by a mutation in the bone morphogenetic protein (BMP) type 1 receptor ALK2 (ACVR1). Sohonos is a retinoic acid receptor agonist which binds the gamma subtype RAR and decreases the BMP/ALK2 downstream signaling pathway. This in turn reduces ALK2/SMAD-dependent chondrogenesis and osteocyte differentiation resulting in reduced endochondral bone formation. Sohonos is the first FDA-approved treatment of FOP. Prior to the approval of Sohonos, standard of care (SOC) for FOP included therapy aimed at symptom relief by decreasing inflammation, and treatment of chronic pain.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Sohonos is a pharmacy benefit that will be managed by GHP and should be added to the GHP Family formulary on the brand tier. The following prior authorization criteria will be required:

- Medical record documentation that Sohonos is prescribed by or in consultation with an endocrinologist or a physician who specializes in connective tissue or bone diseases
- Medical record documentation of a diagnosis of fibrodysplasia ossificans progressive (FOP) AND
- Medical record documentation of confirmed Activin A Type 1 Receptor (ACVR1) R206H mutation AND
- Medical record documentation of age greater than or equal to 8 years for females OR greater than equal to 10 years for males

GPI Level: GPI-12

Authorization Duration: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Require RPH Sign off: Yes. Sohonos will require RPH signoff to ensure appropriate utilization.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Xacduro (sulbactam for injection; durlobactam for injection)

Review: Xacduro (sulbactam and durlobactam) is indicated for patients 18 years and older for the treatment of hospital acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex. Acinetobacter baumannii is resistant to desiccation and disinfectants, which allows it to have developed resistance to most antimicrobial agents. Carbapenem-resistant Acinetobacter baumannii (CRAB), is a gram-negative bacterium and is resistant to broad-spectrum carbapenem drugs: meropenem, imipenem, and doripenem. It can cause infections in the blood, lungs and urinary tract. At risk populations include patients who have wounds being cared for in healthcare settings, immunocompromised, or require invasive medical devices, like urinary or bloodstream catheters or ventilators. In the United States (US), the greatest source of acquiring an infection is from hospitals and other healthcare facilities. It has an estimated 7500 cases per year and in some countries its resistance to carbapenems exceeds 90% and with a mortality of 60%. In 2017 the CDC estimated 8,500 cases among U.S. hospitalized patients, which resulted in 700 deaths, and nearly 281 million dollars in excess healthcare costs

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Xacduro is a medical benefit and should not be added to the formulary for GHP Family. The following additional criteria will apply:

- Medical record documentation of a diagnosis of Hospital-acquired Bacterial Pneumonia (HABP) or Ventilator-associated Bacterial Pneumonia (VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus complex* **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation that Xacduro is prescribed by or in consultation with Infectious Disease **AND**
- Medical record documentation of <u>one</u> of the following:
    - Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to preferred alternative antibiotic treatments or combination therapy depending on severity **OR**
    - Medical record documentation of history of previous intolerance to or contraindication to two (2) preferred alternative antibiotics or combination therapy depending on severity, shown to be susceptible on the culture and sensitivity.

GPI Level: GPI-12
Authorization Duration: 14 days
Require RPH Sign off: Yes

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Ycanth (cantharidin)

Review: Ycanth is indicated for the topical treatment of molluscum contagiosum in adults and pediatric patients 2 years of age and older. Ycanth is a topical solution containing cantharidin, a lipophilic compound, but the exact

mechanism in the treated of molluscum contagiosum is unknown. Cantharidin is a blistering agent previously available through compounding pharmacies.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Ycanth is a medical benefit that will require a prior authorization. The following prior authorization criteria should apply:

- Medical record documentation of age greater than or equal to 2 years AND
- Medical record documentation that Ycanth is prescribed by a dermatologist AND
- Medical record documentation of a diagnosis of molluscum contagiosum (MC)

GPI Level: GPI-12
Authorization Duration: 3 months

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Xdemvy (lotilaner ophthalmic solution)

Review: Xdemvy is the first and only medication approved by the FDA for the treatment of *Demodex* blepharitis (DB). DB is an eyelid condition that is caused by the infestation of mites, *Demodex folliculorum or Demodex brevis,* in the eyelash follicles or meibomian glands. It is estimated that up to 25 million patients in the United States may be affected with DB. DB is characterized by eyelid redness and inflammation with the presence of collarettes or waxy debris at the base of the eyelashes. Prior to Xdemvy, treatment options for patients with DB were limited to eyelid scrubs, warm compresses, and tea tree oil.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Xdemvy will be a pharmacy benefit and should be added to the Geisinger Family formulary at the Brand Tier. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of chronic *Demodex* blepharitis (DB) evidenced by:
    - Presence of at least mild erythema of the upper eyelid margin **AND**
    - Presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination

AND

- Medical record documentation that Xdemvy is prescribed by or in consultation with an ophthalmologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

GPI Level: GPI-14

Authorization Duration: 6 weeks

Note to Reviewer: The clinical trials performed evaluated a 6-week treatment course only. The benefits of a longer treatment course of Xdemvy are unknown. Tarsus has stated that retreatment may be necessary in about 40% of patients at 1 year following initial treatment, so while a longer treatment course is not advisable, retreatment in some patients is likely to be necessary.

Require RPH Sign off: No

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Rezzayo (rezafungin)

Review: Rezzayo is indicated for adult patients who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data for Rezzayo. Rezzayo has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to Candida. Rezzayo is an echinocandin antifungal drug that inhibits the synthesis of 1,3-β-D-glucan, an essential component of fungal cell walls.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Rezzayo is a medical benefit and will be managed by GHP for GHP Family. The following prior authorization criteria should apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a non-neutropenic patient with a diagnosis of candidemia or invasive candidiasis (other than endocarditis, osteomyelitis, or meningitis) **AND**
- Medical record documentation that Rezzayo is prescribed by an infectious disease specialist **AND**
- Medical record documentation that member has limited or no alternative treatment options

Formulary Alternatives: caspofungin, Eraxis*

GPI Level: GPI-12

Authorization Duration: 4 weeks (one course of therapy)

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Veopoz (pozelimabab -bbfg)

Review: Veopoz is a complement inhibitor indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein losing enteropathy (PLE), also known as CHAPLE disease. Veopoz is the first FDA-approved treatment for CHAPLE disease.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Veopoz will be a medical benefit managed by GHP. The following prior authorization criteria will apply:

- Medical record documentation of CD55-deficient protein losing enteropathy (CHAPLE disease) with a confirmed genotype of biallelic CD55 loss-of-function mutation AND
- Medical record documentation of age ≥ 1 year AND
- Prescribed by or in consultation with a hematologist, gastroenterologist, or a provider specialized in rare genetic hematologic diseases AND
- Medical record documentation that the patient is vaccinated with the meningococcal vaccine AND
- Medical record documentation that Veopoz will not be used in combination with Soliris (eculizumab) AND
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Authorization Duration: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression (i.e., improvement or no worsening of clinical symptoms, increase in or stabilization of albumin and IgG concentration)

Require RPH Sign off: Yes

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Class Review

Bevacizumab

Bevacizumab Agents			
Brand Name	**Generic**	**Date approved**	**Manufacturer**
Avastin	**Bevacizumab**	**2/26/2004**	**Genentech**
Mvasi	**Bevacizumab-awwb**	**9/14/2017**	**Amgen**
Zirabev	**Bevacizumab-bvzr**	**6/27/2019**	**Pfizer**
Alymsys	**Bevacizumab-maly**	**4/13/2022**	**Amneal**
Vegzelma	**Bevacizumab-adcd**	**9/27/2022**	**Celltrion**

Recommendation: No changes recommended based on clinical review. The following updates were recommended after financial analysis: Mvasi, Zirabev, Alymsys, and Vegzelma are medical benefits managed by GHP and will

not require prior authorization. Avastin is a medical benefit managed by GHP and will require prior authorization. The following prior authorization criteria and authorization duration for Avastin only will apply:

Medicaid (GHP Family)		
Medication	**Current Policy**	**Recommendations**
Avastin	No prior authorization required	It is recommended that prior authorization (PA) be required. **PA criteria** • Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to all of the following: Mvasi (bevacizumab-awwb), Zirabev (bevacizumab-bvzr), Alymsys (bevacizumab-maly), Vegzelma (bevacizumab-adcd) **Authorization Duration:** For adjuvant treatment of Stage III or IV Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer following initial surgical resection: Authorization will be for one (1) **21 month** approval. Authorization of Avastin for adjuvant treatment should not exceed the FDA-approved treatment duration of 21 months (28 cycles). For requests exceeding the above limit, medical record documentation of the following is required: • Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration For all other indications: Authorization will be open-ended

Outcome: The committee unanimously voted to accept the recommendation.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Fast Facts

Updates

January 2024 P&T DUR/Adherence Update

Outcome: The January 2024 P&T DUR/Adherence Update was presented to the committee for review.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

December ELECTRONIC VOTE
An electronic vote was held from December 12, 2023, to December 22, 2023. Responses were received from 26 members (out of 49 members) and all voted to approve. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Elevidys (delandistrogene moxeparvovec-rokl)

Review**:** Elevidys is an adeno-associated virus (AAV)-based gene therapy that is administered as a one-time, single intravenous (IV) dose. It is approved for the treatment of ambulatory pediatric patients 4 through 5 years of age with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene. It utilizes an adeno-associated virus (AAVrh74) to introduce a shortened version of the DMD gene (encoding Elevidys micro-dystrophin) into muscle tissue, partially compensating for the lack of a functional DMD gene and targeting the underlying genetic defect that causes DMD. This indication is approved under accelerated approval based on expression of Elevidys micro-dystrophin in skeletal muscle observed in patients treated with Elevidys. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Recommendation**:** Elevidys is a medical benefit that is not managed by the PDL. Elevidys will require a PA with the following criteria:.
• Medical record documentation of a diagnosis of Duchenne Muscular Dystrophy confirmed by a genetic mutation in the Duchenne Muscular Dystrophy gene AND
• Medical record documentation that the patient does NOT have a deletion in exon 8 and/or exon 9 in the Duchenne Muscular Dystrophy gene AND
• Medical record documentation that the member is a male based on assigned sex at birth and is at least 4, but no older than 5 years of age AND
• Medical record documentation of provider attestation that the member is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent) AND
• Medical record documentation that Elevidys is prescribed by a neurologist or pediatric neurologist AND
• Medical record documentation that patient has been initiated on corticosteroids* for Duchenne muscular dystrophy one day prior to Elevidys infusion and medical documentation that patient will continue the regimen after for 60 days AND
• Medical record documentation that the patient is on the appropriate weight-based dose**AND
• Medical record documentation that the patient has never received Elevidys treatment in their lifetime AND
• Medical record documentation that the member has not received any previous gene therapy for Duchenne muscular dystrophy AND
• Medical record documentation that the patient will not receive exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly with Elevidys treatment. (Note: Any current authorizations for exon-skipping therapy will be terminated upon Elevidys approval.)

Authorization Duration: One (1) time approval per lifetime.
Reauthorization info: Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

Other Formulary Policy Recommendations:
Due to lack of evidence for combined use, it is recommended to add criterion to the exon-skipping therapies to confirm gene therapy has not previously been given.

It is recommended to add the following criterion to the following policies: MBP 241 Amondys 45, MBP 148 Exondys 51, MBP 226 Viltepso, MBP 214 Vynodys 53, 875.0D Amondys-45, 573.0D Exondys 51, 845.0D Viltepso:
• Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Elevidys)*
Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Roctavian (Valoctocogene Roxaparvovec)

Review: Roctavian is the first gene therapy approved for the one-time treatment of severe hemophilia A and offers a novel treatment option beyond standard-of-care treatments (prophylaxis with FVIII products or Hemlibra). Patients with severe hemophilia A generally receive multiple or once-weekly IV doses of prophylactic FVIII or subcutaneous (SC) administrations of Hemlibra once every 1, 2, or 4 weeks. Treatment with Roctavian has the potential to increase quality of life in these patients because it may free patients from burdensome FVIII IV infusions or scheduled Hemlibra SC injections. Roctavian is unlikely to represent a cure for hemophilia A due to its current durability data, as FVIII activity (which tends to correlate to protection against bleeds) decreases over time in clinical trials.

Recommendation: Roctavian will be a medical benefit. Roctavian will require a prior authorization with the following criteria.
- Medical record documentation that the patient is a male based on assigned sex at birth and age greater than or equal to 18 years AND
- Medical record documentation that the patient is diagnosed with severe hemophilia Aa AND
- Medical record documentation that Roctavian is being dosed according to the Food and Drug Administration approved labeling for hemophilia Ab AND
- Medical record documentation that the member has not received any previous gene therapy for hemophilia A AND
- The prescription must be written with consultation from or by a Hematologist AND
- Medical record documentation showing lack of pre-existing antibodies to AAV5 using the FDA approved companion diagnosticc AND
- Medical record documentation of factor VIII inhibitor titer testing showing lack of factor VIII inhibitor AND
- Medical record documentation whether a patient can receive corticosteroids and/or other immunosuppressive therapy that may be required for an extended period AND
- Medical record documentation that the patient DOES NOT have active acute or uncontrolled chronic infections, known significant hepatic fibrosis (stage 3 or 4 on the Batts-Ludwig scale or equivalent) or cirrhosis, or mannitol hypersensitivity AND
a. Severe hemophilia A: Factor VIII activity <1% (<0.01 units/mL) with spontaneous bleeding into joints or muscles
b. Dose Calculation:
1. To determine a patient's dose in milliliters, multiply the patient's body weight in kilograms by 3 = dose in milliliters.
2. To determine the number of Roctavian vials to be thawed divide the patient dose volume (in milliliters) by 8 = number of vials to be thawed (always round up to the next whole number).

Table 1: Example of Dose Volume and Number of Vials to be Thawed

Patient Weight	***Patient Dose by Volume (mL) (body weight multiplied by 3)***	***Number of Vials to be Thawed (dose volume divided by 8, then rounded up)***
70 kg	***210 mL***	***27 vials (rounded up from 26.25)***

c. The FDA companion diagnostic for Hemophilia A is the AAV5 DetectCDx produced by ARUP Laboratories. This diagnostic detects antibodies to the adeno-associated virus serotype 5 (AAV5) viral vector.

Authorization Duration: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Dengvaxia (Dengue Tetravalent Vaccine, Live)

Updated Indication: Dengvaxia® (Dengue Tetravalent Vaccine, Live) is a vaccine indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3, and 4. Dengvaxia is now approved for use in individuals 6 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas.

Recommendation: Dengvaxia will remain covered under medical benefit only through the Vaccines for Children (VFC) program.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Keytruda

Updated Indication: Keytruda is now indicated for the treatment of resectable (tumors ≥4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.

Recommendation: The following prior authorization criteria and changes should be added to MBP 119.0.

Neoadjuvant/Adjuvant Treatment of Resectable NSCLC
• Prescription written by a hematologist/oncologist AND
• Medical record documentation of resectable (Tumors ≥ 4 cm or Node Positive) non-small cell lung cancer (NSCLC) **AND**
• Keytruda is being used in the neoadjuvant setting in combination with platinum containing chemotherapy then continued as a single agent in the adjuvant setting following resection
OR
• Medical record documentation of Stage IB (T2a ≥ 4 cm), II, or IIIa non-small cell lung cancer (NSCLC) **AND**
• Keytruda is being used as a single in the adjuvant setting following resection and platinum-based chemotherapy

8.Gastric Cancer
• Prescription written by a hematologist/oncologist **AND**
• Medical record documentation that Keytruda will be used as first-line treatment **AND**
• Medical record documentation of one of the following:
a. Medical record documentation of a diagnosis of locally advanced unresectable or metastatic HER-2 positive gastric or gastroesophageal junction adenocarcinoma **AND**

b. Medical record documentation that tumors express PD-L1 (CPS≥1) as approved by an FDA approved test **AND**

c. Medical record documentation that Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy **AND**

OR

- Medical record documentation of locally advanced unresectable or metastatic HER-2 negative gastric or gastroesophageal junction (GEJ) adenocarcinoma AND
- Medical record documentation that Keytruda will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

Biliary Tract Cancer

1. Prescription written by a hematologist/oncologist **AND**
2. Medical record documentation of locally advanced unresectable or metastatic biliary tract cancer **AND**
3. Medical record documentation that Keytruda will be used in combination with gemcitabine and cisplatin

For adjuvant treatment of metastatic melanoma (completely resected melanoma), neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer, neoadjuvant/adjuvant treatment of non-small cell lung cancer, and adjuvant treatment of renal cell carcinoma:
Initial approval will be for 6 months. One subsequent approval will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.
Authorization of Keytruda for the adjuvant treatment of metastatic melanoma, of non-small cell lung cancer, and of renal cell carcinoma should not exceed the FDA-approved treatment duration of 1 year (12 months). Authorization for the treatment of neoadjuvant/adjuvant treatment of non-small cell lung cancer should not exceed the approved treatment duration of 12 weeks of neoadjuvant treatment and 39 weeks of adjuvant therapy. Authorization of Keytruda for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy. For requests exceeding the above limit, medical record documentation of the following is required:
• Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Opdivo

Updated Indication: Opdivo is now approved for the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma.

Recommendation: It is recommended to update the following criteria as a result of the new indication.

Medical Benefit Policy 126.0 (Opdivo)

Melanoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 12 years of age **AND**
- Medical record documentation of one of the following:

- A diagnosis of unresectable or metastatic melanoma **AND**
- Opdivo is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma (with the exception of ipilimumab).

OR

- A diagnosis of completely resected (no evidence of disease) ~~metastatic melanoma with distant metastases, which may include lymph nodes~~ Stage IIB, Stage IIC, Stage III, or Stage IV melanoma **AND**
- ~~Medical record documentation of complete resection of distant metastases **AND**~~
- Opdivo is being used in the adjuvant setting **AND**
- Opdivo is being used as a single agent

  ***(*Note: The FDA-approved treatment duration for use of Opdivo in the adjuvant setting for completely resected ~~metastatic~~ stage IIB, stage IIC, stage III, and stage IV melanoma is for up to 1 year, see specific reauthorization criteria below.)*

AUTHORIZATION DURATION:

****For adjuvant treatment of ~~metastatic~~ melanoma *(completely resected melanoma*), adjuvant treatment of resected esophageal or gastroesophageal junction cancer, and adjuvant urothelial carcinoma:**

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **6 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Opdivo for the adjuvant treatment of ~~metastatic~~ melanoma, adjuvant treatment of resected esophageal or gastroesophageal junction cancer, or adjuvant treatment of urothelial carcinoma should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Meeting adjourned at 4:02 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on March 19, 2024 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams